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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,896	12/21/2001	Viktor Roschke	PA004P1	5432

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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,896	ROSCHKE, VIKTOR	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed September 9, 2004, have been fully considered and they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 25-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

4. The rejection under 35 U.S.C. 101 cited in the previous office action is maintained in the instant office action.

5. The Examiner disagrees with the applicant that the asserted utility of the claimed invention is specific. The Applicant cited page 49, line 9 of the specification that states that the polypeptides are primarily expressed in breast tissue. However, Applicant did not the address the rest of page 49 in lines 17-20 which states, "...expression of this gene at significantly higher or lower levels may be routinely detected in *certain tissues* or *cell types* (e.g., breast, *reproductive*, *cancerous* and *wounded tissues*) or bodily fluids (e.g., breast milk, *lymph*, *serum*, *plasma*, *vaginal pool*, *urine*, *synovial fluid* and *spinal fluid*)...." (emphasis added). The emphasized words in this passage clearly state that

the gene product is expressed in other tissues other than the human breast. Since certain undefined tissues and cell types express this gene product, one of skill in the art must perform additional research to determine the identity of these tissues, cell types, or bodily fluids. In addition, the specification states that higher or lower levels of the gene expression product may be detected in tissues, cells, or bodily fluids from individuals with or without disorders. One of skill in the art must perform additional research to determine what diseases or disorders the polynucleotides and polypeptides could identify. Although the applicant states that the gene product is expressed primarily in breast tissue, the word "primarily" does not lend any more specificity to the utility of the invention especially in light that the gene product is also expressed in other tissues and cell types.

6. The Examiner also disagrees with the applicant that the asserted utility of the claimed invention is substantial. The applicant states that using the claimed invention for diagnosis and/or treatment of breast cancer is a substantial utility. However, the gene product is expressed in many types of tissues and cells. Thus for practitioner to diagnose breast cancer, a practitioner must first distinguish from which cells or tissues do these gene products are produced. The practitioner would have to conduct further experimentation to be able to diagnosis breast cancer using the claimed invention. In addition, the breast cancer cells and normal breast tissue produce the same gene products in the same quantities. Without any means of evaluating if the gene product is from a person with a disorder, the practitioner once again would have to conduct further experimentation. Because the specification does not disclose how one would

distinguish the gene product of the claimed invention from breast tissue, breast cancer, or other certain tissues or cell types, the utility of the invention is not substantial.

7. The Applicant also points out that all the Applicant is required to demonstrate that this is a reasonable correlation between the biological activity and the assert utility. As the Examiner stated above, breast cancer and normal breast tissue produce the same gene products in the same quantities. In addition, the specification states that the gene products are found in certain tissues and cell types. Thus, there is no correlation between the biological activity of the claimed invention and the utility of the diagnosing breast cancer. The asserted utility is not specific or substantial.

8. The Applicant also points out that therapeutic inventions may be useful despite the requirement for further research and development. However, what the applicant is pointing out does not address the issue of whether the asserted utility is specific, substantial and credible. Even if further research or development was not necessary, the Applicant must still meet the specificity, substantiality and credibility requirements to demonstrate utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and

credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Status of the Claims

Claims 1-24 cancelled.

Claims 25-36 pending.

Claims 25-36 rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:30-7:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JL

Ardin H. Marschel 12/9/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER